

DAIDS/VRP Vaccine Development Resources Proposal Template

To aid you in preparing an application for support from Vaccine Developmental Resources (VDR):

Your application should address the following:

- Vaccine concept
- Construct description – design, manufacture summary (e.g., if grown in a cell substrate, what is it? Where did the vector come from? Does it require an adjuvant for potency? etc.), first generation/second/etc.
- Rationale – in vitro and in vivo data (e.g., immunogenicity data, dose rationale, schedule justification, route of administration justification) – if these data were obtained with constructs other than the construct for which you are requesting support, please clarify
- Safety – in vitro and in vivo data - if these data were obtained with constructs other than the construct for which you are requesting support, please clarify
- Product details – see below
- Brief clinical plan (general investigational plan)
- List of what resources you are requesting (e.g., pre-clinical toxicology, pre-IND preparation, GMP manufacture, IND preparation) – this list should not overlap with existing funding an estimated budget should be provided

In order for the VDR process to best gauge the developmental stage of your product, please provide the following information:

- Description of manufacturing processes/steps (useful to include flowchart)
- Any data on formulation optimization and stability, including use of any adjuvants
- Description and discussion of raw material and biological starting material suitability, quality, and characterization (e.g., passage history of cell substrate and viral seed material) including any master or working banks or seeds already prepared
- List and descriptions of proposed lot release and characterization assays
- Any characterization data already attained
- Discussion of any assay development required to support lot release or product characterization, including but not limited to:
 - Potency
 - Safety (e.g., detection of replication competent recombinants)
- Preparation of reagents needed to develop assays (e.g., monoclonal antibodies, PCR primers and probes, peptides)
- Description of progress in product development, including planning (e.g., consultation on product characterization, formulation, manufacture, etc.; anticipated timelines for development) and description of any lots already manufactured (successful? pilot? tox? clinical?)

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- Discussion of any regulatory or practical limitations of starting materials, construct, manufacturing processes, or proposed clinical plan (e.g., scalability, acceptability of cell substrate or bovine serum history/traceability, stability, special clinical safety assays)
- Description of specific manufacturers, if any, with whom you propose to develop product